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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,231	11/17/2000	Susan R. Webb	TSRI 536.1 Div1	7187

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THE SCRIPPS RESEARCH INSTITUTE
10550 North Torrey Pines Road
Mail Drop: TPC-8
La Jolla, CA 92037

EXAMINER

DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/15/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/715,231

WEBB ET AL.

Examiner

Amy M. DeCloux

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 26 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-60 is/are pending in the application.
- 4a) Of the above claim(s) 34,37,38,48,49,53-55 and 58-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33,35,36,39-47,50-52,56 and 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 33-60 and the species of a cell, a costimulatory molecule, B7.1, and an adhesion molecule, ICAM-1, in Paper No. 7, filed 4-26-02, is acknowledged. The traversal is on the ground(s) that the generic claims recite a multiplicity of species that do not require an unduly extensive and burdensome search. This is not found persuasive because each of the species of the generic synthetic antigen presenting matrix recited in the generic claims encompasses a matrix of different components. As such, though the searches for each species overlap somewhat, said searches are not co-extensive and as such would constitute an undue burden to the examiner as outlined in the restriction requirement mailed 3-26-02, Paper No.6 .

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 34, 37-38, 48-49, 53-55, 58-60 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7, filed 4-26-02.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

4. New formal drawings are required in this application because of the reasons in the attached PTO Form 948. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a

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Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

3. Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Specification

5. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 or 119(e) as follows:

The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ 2d 1077 (Fed. Cir. 1994).

Specifically, there is no support for the phrase recited in either part B or Part C of independent claim 33, and its dependent claims.

Applicant is invited to point out support in said provisional for said claims.

Oath/Declaration

6. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
the declaration claims priority under 35 USC 120 to a provisional application and fails to claim priority under 35 USC 119() to provisional US application 60/018,175.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 33, 35-36, 39-43, 45-47, 50-52 and 56-57 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to a synthetic antigen presenting matrix comprising a support, an extracellular portion of a MHC Class II heterodimer and an accessory molecule. The instant disclosure of "a synthetic antigen presenting matrix" and "an accessory molecule" do not adequately describe the scope of each claimed genus, each of which encompasses a substantial variety of subgenera. With the exception of insect cells and the accessory molecules of B71.1, B71.2, ICAM-1, ICAM-2 ICAM-3, FASL, CD70 and LFA, there is no description in the instant specification of the required structural and specific functional features of said broad genus of synthetic antigen presenting matrix that would meet the recited limitations of antigen presentation. Neither is there a disclosed description of the structural features that would be attributed to an accessory molecule. Further, the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify a synthetic antigen presenting matrix or accessory molecule encompassed by the instant claims, with the exception of insect cells and the accessory molecules of B71.1, B71.2, ICAM-1, ICAM-2 ICAM-3, FASL, CD70, and LFA, as disclosed in the instant specification on page 8, lines 18-19. Therefore, the structure of "a synthetic antigen presenting matrix" and "an accessory molecule" is not conventional in the art and one of skill in the art would not recognize from the disclosure that applicant was in possession of the genus of "a synthetic antigen presenting matrix" and "an accessory molecule" encompassed by the method of the claimed invention.

It is noted that though the claimed invention encompasses a genus of synthetic antigen presenting matrix and an accessory molecule, and not cDNA, the principle of the following still holds for said cells and genes : a description of a genus of cDNAs may be achieved by

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means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 33, 35-36, 41-43, 44-47, 50-52 and 56-57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,355,479. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims in the '479 patent is more narrow than the scope of the claims in the instant application.

Instant claim 33, 35, 36, 41-42, 44-47, 50-52 and 56-67 are drawn to a synthetic antigen presenting matrix for activating CD4⁺ T cells comprising a support wherein the support is a cell, comprising an extracellular portion of a MHC Class II heterodimer, operably linked to the support and capable of loading a selected peptide, and an extracellular portion of at least one accessory molecule operably linked to the support. Said instant pending claims 33, 35-36, 41-

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43, 44-47, 50-52 and 56-57 differ from claims 1, 8, 9, 11-13, 17, 18-22 of '479 only in the scope of the encompassed subject material. In the '479 patent, an insect synthetic antigen presenting is recited in independent claim 1 and dependent claims, 8, 9, 11-13, 17, 18-22, wherein the pending instant independent claim 33 and dependent claims 35, 36, 41-42, 44-47, 50-52 and 56-67 recite a synthetic antigen presenting matrix, wherein the elected species is any cell. The limitations in the dependent claims of both the patent and the instant application are essentially identical.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

12. Claims 33, 35-36, 41-42, 44-47, 50-52 and 56-57 are rejected under 35 U.S.C. 102(e) as being anticipated by MacKay et al. US Patent 5,648,219.

'219 teaches isolated synthetic antigen presenting matrix comprising a support wherein said support is a cell which is comprised of JAWS II dendritic cells transfected with MHC Class II and which has been activated and expresses an extracellular portion of at least one of CD80 (B7.1) CD86 (B7.2 and ICAM-1, in sufficient numbers for activating CD4+ T cells when a peptide (GAD) is loaded with exogenous peptide, see entire patent especially claims 7, 9 and 11, and column 8, lines 47-60 and column 15, lines 35-62). Therefore, the referenced teachings anticipate the claimed invention.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, PhD,
Patent Examiner, Group 1640,
July 14, 2002

Amy DeCloux 7-15-02